

Summary of Safety and Effectiveness

510(k) Summary: UASS II

MAY 23 2003

SPONSOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

CONTACT PERSON: Janet A. McGrath
Senior Regulatory Affairs Specialist

Or

Lorraine M. Hanley
Director Regulatory Affairs

DEVICE: Ureteral Access Sheath Set II

TRADE NAME: Navigator™ Access Sheath Set

COMMON NAME: Ureteral Access Sheath Set

CLASSIFICATION: Class II; 876.1500, Endoscope and Accessories
Class II; 876.5130, Urological Catheter and Accessories

PREDICATE DEVICE: Ureteral Access Sheath Set

DESCRIPTION: The UASS II is designed to create a conduit for urological procedural instruments. This set consists of two components: an inner tapered semi-rigid dilator and an outer more flexible sheath. The outer flexible sheath fits over the semi-rigid inner dilator and it may be locked into place. These components are radiopaque and have a lubricous hydrophilic coating. The device is offered in two French sizes, 11/13 Fr, and 13/15 Fr. in lengths up to 46cm.

The UASS II may be placed retrograde and/or antegrade. To guide the access sheath into the body orifice the dilator is advanced over up to a .038" guidewire. The device can be visualized under x-ray (fluoroscopy) during placement to confirm location. The proposed device can accept other urological instrumentation with OD's compatible with the sheath's working channel of 11 and 13 Fr, respectively.

The proposed device is provided sterile single use. The packaging materials used for the proposed UASS are commonly used materials for packaging medical devices and similar to the predicate device. The device will be packaged in a labeled, single

polyfilm/tyvek peel pouch double sealed, which will be placed in a labeled, paperboard shelf carton.

INTENDED USE:

The UASS II is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract antegrade and/or retrograde access.

**TECHNOLOGICAL
CHARACTERISTICS:**

The proposed device is substantially equivalent in design and materials to previously cleared devices. The proposed device has hydrophilic coating to facilitate device placement and withdrawal.

PERFORMANCE DATA:

Results of physical comparison and functional testing support a determination of substantial equivalence for the proposed device when compared to the predicate device. The proposed device is substantially equivalent to devices previously cleared via the 510(k) path in terms of technology, principles of operation, intended use, and materials.



MAY 23 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Janet A. McGrath
Senior Regulatory Affairs Specialist, Urology
Microvasive Urology
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K030956

Trade/Device Name: Ureteral Access Sheath Set II
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Product Code: 78 KOD
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: 78 KOG
Regulatory Class: II
Dated: May 2, 2003
Received: May 5, 2003

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known):

K030956

Device Name: UASS II

Indications for Use:

Indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract via antegrade and/or retrograde access.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR

Over-The-Counter Use
(Optional Format 1-2-96)

David G. Regan
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K030956